Ongoing Guidance development within MDCG Subgroups – October 2019*

**This is not an exhaustive list of ongoing work performed by MDCG subgroups*

Scope	Group Deliverables	Consult prior to MDCG**	Planned MDCG Endorsement	Additional Comments
*** Stakeholders are observers in 11 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated*				
1. Notified Bodies Oversight (NBO)[1]				
MDR + IVDR	*Q&A on Notified bodies –new questions to be added to the document already published*		2020	
MDR + IVDR	*Sampling of devices on a representative basis*	IVD, UDI, Nomenclature, CIE	2019	
MDR + IVDR	*Explanatory note on codes*	IVD	2019	
MDR + IVDR	*Batch verification on class D IVDs*	IVD	TBD	
MDR+IVDR	*Significant changes*	TBD	TBD	Task force to be set up
MDR	*Applicability of clinical evaluation consultation procedure*	CIE	TBD	Kick off meeting of the TF on 13/09/2019
2. Standards				
MDR + IVDR	*Commission Implementing Decision (Standardisation request)*	N/A	2019	

[1] Stakeholders are not part of this group as it covers requirements set out by designating authorities specifically for Notified Bodies; stakeholders are consulted on mature and final drafts.

3. Clinical Investigations and Evaluation (CIE)				
MDR	*Clinical Evaluation - Equivalence*	NBO	TBD	Currently under extended consultation within the Work Package
MDR	*Clinical evidence needed for medical devices previously certified under Directives 93/42/EC and 90/385/EC (legacy medical devices)*	NBO	TBD	Currently under extended consultation within the Work Package
MDR	*Clinical evaluation assessment report template*	NBO	TBD	
MDR	*Clinical investigation application*	N/A	2019	Input to EUDAMED CIE
MDR	*Clinical investigation assessment template*	N/A	2019	Input to EUDAMED CIE
MDR	*Processes and templates relative to CI and PS Assessments*	N/A	2019	Input to EUDAMED CIE
MDR	*Template Post-Market Clinical Follow-up Plan*	NBO, PMSV	2019	
MDR	*Template Post-Market Clinical Follow-up Plan Update*	NBO, PMSV	2019	
MDR	*SAE reporting EUDAMED requirements - form*	N/A	2019	Input to EUDAMED CIE
MDR	*Report form for Serious Adverse Events*	N/A	2019	Input to EUDAMED CIE
MDR	*Process flow for SAE reporting*	N/A	2019	Input to EUDAMED CIE
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	*Post-Market Surveillance requirements*	CIE	TBD	Task Force to be set up

MDR + IVDR	*Vigilance requirements*	CIE	TBD	Task Force has been set up
MDR + IVDR	*Development of harmonised reporting forms for incidents*	CIE	TBD	Several Task Forces on-going
5. Market Surveillance (MS)[2]				
MDR	*Class I manufacturers*	CIE / PMSV	2019	
MDR + IVDR	*Update of PRRC document*	TBD	2020	
MDR + IVDR	*Authorised Representatives*	TBD	2020	Task force has been set up
MRD + IVDR	*In-house manufacturers*	IVD	TBD	Task force to be set up
6. Borderline & Classification (B&C)				
MDR	*Borderline with medicinal products (including general guidance, definitions of pharmacological, immunological and metabolic means of action and diagnosis, and consultation procedures of medicines authorities)*	NBO	TBD	
MDR	*Classification of medical devices*	NBO / NET	TBD	NET involved in drafting sections of the document
7. New Technologies				
MDR + IVDR	*Clinical Evaluation of Software*	CIE+IVD	2019	
MDR + IVDR	*Cybersecurity of Software*	N/A	TBD	

[2] Stakeholders are not part of this group as it covers requirements set out by competent authorities; stakeholders are consulted on mature and final drafts.

8. EUDAMED				
Group yet to be established under MDCG				
9. Unique Device Identification (UDI)				
MDR + IVDR	*Integration of UDI in manufacturers' QMS*	N/A	2019	
MDR + IVDR	*Guidelines on specific product types (contact lenses)*	N/A	2019	Part of bilateral cooperation with US
MDR + IVDR	*Formats of AICD and HRI parts of UDI carriers*	N/A	N/A	To be available and published by Oct 2019
MDR + IVDR	*List of values for certain data fields (clinical size + warnings and contraindications)*	CIE + IVD	N/A	
10. International Matters				
MDR + IVDR	*Taking into account MDSAP for NB*	NBO	TBD	
11. In vitro Diagnostic Medical Devices (IVD)				
IVDR	*Classification of IVDs*	BC, NBO	2019	
IVDR	*Performance evaluation*	CIE	TBD	
IVDR	*SSP template and guidance*	CIE	TBD	
IVDR	*Transfer of CTS to CS*	N/A	TBD	
IVDR	*Development of common specifications*	N/A	TBD	

IVDR	*Qualification of assays used in clinical trials of medicinal products*	N/A	TBD	In collaboration with competent authorities for medicinal products
12. Nomenclature				
MDR + IVDR	*Information package on EMDN (for website)*	N/A	N/A	To be published by Q4 2019
MDR + IVDR	*Rules and process for update of EMDN*	N/A	2019	
MDR + IVDR	*1st release of EMDN*	N/A	TBD	
MDR + IVDR	*Mapping CND-GMDN package*	N/A	N/A	To be possibly finalised by 2020 Q2. The outcome of this exercise is highly dependent on level of cooperation ensured by GMDN
MDR + IVDR	*Translation of EMDN*	N/A	TBD (validation)	Experts from MS; might be conducted by the translators in the course of the translation exercise
MDR + IVDR	*List of EMDN terms to be used for implant card purposes*	UDI	2019	
13. Annex XVI[3]				
MDR	*Qualification of devices listed in Annex XVI*	TBD	TBD	

[3] Stakeholders are not part of this group as it covers requirements set out by competent authorities; stakeholders are consulted on mature and final drafts. text